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10/562,195	12/23/2005	Steven Walter Clavey	50438/002001	4118

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CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER

CLARK, AMY LYNN

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

07/17/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/562,195

Applicant(s)

CLAVEY, STEVEN WALTER

Examiner

Amy L. Clark

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 February 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 3-25 is/are pending in the application.
4a) Of the above claim(s) 3-9, 13, 14 and 16-25 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 10-12 and 15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 26 February 2008 with amendment of claims 1, 10, 12 and 15 and the cancellation of claim 2.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1 and 3-25 are currently pending.

This application contains claims 3-9, 13, 14 and 16-25 drawn to an invention nonelected without traverse in the reply filed on 26 February 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 10-12 and 15 are currently under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

Newly amended claims 1, 10-12 and 15 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for treating gynecopathy comprising Chi Shao (*Paeonia obovata*) root, Dang Gui (*Angelica polymorpha*) root, Chuan Xiong (*Ligusticum wallichii*) root, Xiang Fu (*Cyperus rotundus*) rhizome, Yah Hu Suo (*Corydalis turtschaninovii*) rhizome and Tao Ren (*Prunus persica*)

Art Unit: 1655

seed, and while also being enabling for a composition for treating symptoms of endometriosis and for treating the side effects of Danocrine™ comprising Fu Ling (*Poria cocos*, Sclerotium), Ze Xie (*Alisma plantago-aquatica*, Rhizome), Dang Gui (*Angelica polymorpha*, Radix), Bai Zhu (*Atractylodes macrocephala*, Rhizoma), Xiang Fu (*Cyperus rotundus*, Rhizome), Yan Hu Suo (*Corydalis turtschaninovi*, Rhizome), Gan Cao (*Glycyrrhizae uralensis*, Radix), He Huan Pi (*Albizia julibrissin*, bark), Yu Jin (*Curcumae*, Tuber), Ren Dong Teng (*Lonicerae Japonicae*), Ramus, Chuan Lian Zi Meliae Toosendan, Fructus Fo Shou Pian Citrii Sarcodactylis, Fructus Ban Xia (*Pinelliae Temata*), Rhizome, Shi Chang Pu (*Acori Graminei*, Rhizoma), Shen Qu (*Massa Fermentata*), wherein the composition is administered in a decoction in the morning and evening followed by a composition comprising: Chi Shao (*Paeonia obovata*, Radix), Bai Shao (*Paeonia lactiflora*, Radix), Fu Ling (*Poria cocos*, Sclerotium), Ze Xie (*Alisma plantago-aquatica*, Rhizoma), Dang Gui (*Angelica polymorpha*, Radix), Bai Zhu (*Atractylodes macrocephala*, Rhizome), Chuan Xiong (*Ligusticum wallichii*, Radix), Xiang Fu (*Cyperus rotundus*, Rhizoma), Yan Hu Suo (*Corydalis turtschaninovi*, Rhizoma), Gan Cao (*Glycyrrhizae uralensis*, Radix), He Huan Pi (*Albizia julibrissin*, bark), Chai Hu (*Bupleurum falcatum*, Root), Chen Pi (*Citrus Reticulata*, pericarpium), Fo Shou Pian Citrii Sarcodactylis, Fructus, Chuan Lian Zi Meliae Toosendan, Fructus, Hong Teng (*Caulis Sargentodoxae Cuneatae*, and Gui Zhi (*Cinnamomi Cassiae*, Ramulus), does not reasonably provide enablement for a composition for treating or alleviating a symptom resulting from a gynecological disorder, comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong

Art Unit: 1655

(*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof.

This rejection is maintained for reasons of record set forth in the paper mailed on 26 November 2007 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 26 February 2008.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The claims are drawn to a composition for treating or alleviating a symptom resulting from a gynecological disorder, comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu

Art Unit: 1655

Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof.

Breadth of the Claims: The claims are broad in that a composition comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof may be administered to treat or alleviate a symptom resulting from a gynecological disorder, in a patient. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes a composition for treating the symptoms of endometriosis and for treating the side effects of Danocrine™ comprising Fu Ling (*Poria cocos*, Sclerotium) in an amount of 12 g, Ze Xie (*Alisma plantago-aquatica*, Rhizome) in an amount of 15 g, Dang Gui (*Angelica polymorpha*, Radix) in an amount of 12 g, Bai Zhu (*Atractylodes macrocephala*, Rhizoma) in an amount of 12 g, Xiang Fu (*Cyperus rotundus*, Rhizome) in an amount of 12 g, Yan Hu Suo (*Corydalis turtschaninovii*, Rhizome) in an amount of 12 g, Gan Cao (*Glycyrrhizae uralensis*, Radix) in a amount of 3 g, He Huan Pi (*Albizzia julibrissin*, bark) in an amount of 15 g, Yu Jin (*Curcuma*, Tuber) in an amount of 12 g, Ren Dong Teng (*Lonicerae Japonicae*, Ramus) in an amount of 18 g, Chuan Lian Zi Meliae Toosendan, Fructus 12 g Fo Shou Pian Citrii Sarcodactylis, Fructus 6 g Ban Xia (*Pinelliae Ternata*), Rhizome an amount of 12 g, Shi Chang Pu (*Acori Graminei*, Rhizoma) in an amount of 12 g, Shen Qu (*Massa Fermentata*) in an amount of 15 g ,

Art Unit: 1655

wherein the composition is administered in an amount of 100 mls of decoction in the morning and evening followed by a composition comprising: Chi Shao (*Paeonia obovata*, Radix) in an amount of 9 g, Bai Shao (*Paeonia lactiflora*, Radix) in an amount of 9 g, Fu Ling (*Poria cocos*, Sclerotium) in an amount of 15 g, Ze Xie (*Alisma plantago-aquatica*, Rhizoma) in an amount of 12 g, Dang Gui (*Angelica polymorpha*, Radix) in an amount of 12 g, Bai Zhu (*Atractylodes macrocephala*, Rhizome) in an amount of 15 g, Chuan Xiong (*Ligusticum wallichii*, Radix) in an amount of 12 g, Xiang Fu (*Cyperus rotundus*, Rhizoma) in an amount of 12 g Yan Hu Suo *Corydalis turtschaninovii*, Rhizoma 2 g Gan Cao *Glycyrrhiza uralensis*, Radix 3 g He Huan Pi *Albizia julibrissin*, bark 15 g Chai Hu *Bupleurum falcatum*, Root 6 g Chen Pi *Citrus Reticulata*, pericarpium 6 g Fo Shou Pian *Citrii Sarcodactylis*, Fructus 6 g Chuan Lian Zi *Meliae Toosendan*, Fructus 9 g Hong Teng *Caulis Sargentodoxae Cuneatae* 18 g Gui Zhi *Cinnamomi Cassiae*, Ramulus 9 g, does not reasonably provide enablement for a composition for treating or alleviating a symptom resulting from a gynecological disorder, comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof.

The specification envisions that a composition comprising Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof will

Art Unit: 1655

have utility in humans to treat or alleviate a symptom resulting from a gynecological disorder.

However, no working examples are provided with regard to a composition comprising Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof to treat or alleviate a symptom resulting from a gynecological disorder. Furthermore, no working examples are provided that demonstrate the efficacy of a composition comprising Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof to treat or alleviate a symptom resulting from a gynecological disorder.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, genital herpes is regarded by the NIH (NICHD) as a gynecological disorder and has many unpleasant symptoms and side-effects, such as lesions or sores, pain and systemic illness. Stanberry et al. (U*) teaches that for many patients with first-episode genital herpes that the first-episode is associated with severe symptoms, such as pain and systematic illness and that the severity of the disease cannot be predicted at first presentation. Stanberry further teaches that treatment of the symptoms of herpes are oral, such as with the oral medication, acyclovir, which is administered five times a day, but that if oral

Art Unit: 1655

treatment is ineffective, that the medication may be administered intravenously.

Stanberry further teaches that treating the first episode helps the patient overcome the initial symptoms but those with genital herpes are likely to have recurrences and that the therapies administered for treatment of the first episode does not affect the frequency or severity of recurrences (See page 6, "Treatment of the first episode").

Since it appears that genital lesions and other symptoms arising from a genital herpes infection are difficult to treat, it is not clear that the claimed composition would have this effect, particularly since the specification does not provide any working examples.

Gormley (V*) teaches that despite an ever increasing volume of literature on outcomes of surgical correction of stress urinary incontinence, the question regarding which procedure has the best outcome is still not answered. Please note that stress urinary incontinence is a symptom resulting from a gynecological disorder and that since urinary incontinence appears to be currently only treatable by surgery, and that the best surgical procedure for treating this symptom is still not known, it is not clear that the claimed composition would have this effect, particularly since the specification does not provide any working examples.

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a composition comprising the herbs: Chi Shao (Paeonia obovata, Root), Dang Gui (Angelica Polymorpha, Root), Chuan Xiong (Ligusticum Wallichii, Root), Xiang Fu (Cyperus Rotundus, Rhizome), Yah Hu Suo (Corydalis turtschaninovi, Rhizome) and Tao Ren (Prunus persica, Seed), or parts thereof may be administered to treat or alleviate a symptom resulting from a

Art Unit: 1655

gynecological disorder. The Office further notes that while the specification discloses that the claim designated composition will have utility in humans to treat or alleviate a symptom resulting from a gynecological disorder, nowhere in the specification or in the limitations does Applicant direct the claimed subject matter to the administration of a composition comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof may be administered to any subject.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to make and use a composition comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof to treat or alleviate a symptom resulting from a gynecological disorder in humans. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify a composition comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 1, 10-12 and 15 are not considered to be fully enabled by the instant specification.

Please note that the main enablement issue is that Applicant is claiming that the instantly claimed composition can treat or alleviate a symptom resulting from a gynecological disorder. There are many symptoms that arise from many different types of gynecological disorders, as discussed above (such as lesions or sores, pain and systemic disease which are symptoms of genital herpes, which is a gynecological disease, and urinary incontinence, which is a symptom of a gynecological disease, such as menopause). Therefore, Applicant should consider the scope disclosed within the originally filed specification and make amendments to the claims accordingly. Also, another issue is that Applicant is claiming specific plants and their specific parts next to the specific herbs but then says, "or parts thereof" in line 8 of claim 1. Applicant is directed to the specification to pick and choose the specific plant parts used in Applicant's invention and to determine what composition of these specific plant parts is enabled by Applicant's originally filed specification.

Please further note that the art rejection provided below is with regards to a different intended use, so despite the fact that the art teaches a composition for treating gynecological conditions, such as female sterility, by administering compositions comprising the claim designated ingredients and not a composition for treating or

Art Unit: 1655

alleviating a symptom resulting from a gynecological disorder, the art still teaches the claimed composition.

Applicant argues that Applicant has amended the claims to recite a specific composition and that the intended use has been removed to have the claims comply with the U.S. claim style and because the intended use does not limit the contents of the composition. Applicant further argues that given the teachings of the specification, one of skill in the art would be able to practice the claimed invention without undue experimentation.

However, this is not found persuasive for the reasons provided in the previous Office Action and for the reasons set forth above. With regards to whether or not intended use is recited in the claims, the specification alleges that the composition is capable of treating all types of gynecological disorders; however, Applicant is not enabled for that broad scope of intended use. Furthermore, with regards what Applicant is enabled for based upon the specification and what was known in the art, Applicant is limited to the specific compositions that have been tested in the specification and to any combination of ingredients known in the art to have a particular intended use, irrespective of whether Applicant has disclosed the intended use in the claims or not. The art teaches that the ingredients claimed by Applicant were useful in treating gynecopathy (See previous Office Action and the rejection below).

Therefore, the rejection remains for reasons of record and for the reasons set forth below.

Claim Rejections - 35 USC § 103

Newly amended claims 1, 10-12 and 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al. (N*, CN 1303689 A, Abstract only), in view of Cai (O*, CN 1223119 A, Abstract only), Li et al. (P*, CN 1074611 A, Abstract only), Zhang (Q*, CN 1240143 A, Abstract only), Jenkins et al. (W*, "Packaging Drugs and Pharmaceuticals") and Beckman (X*, "Pharmacology: The Nature, Action and Use of Drugs").

This rejection is maintained for reasons of record set forth in the paper mailed on 26 November 2007 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 26 February 2008.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Gong teaches a Chinese medicine preparation for curing gynecopathy, which is defined as any of various diseases occurring in women, comprising cyperus rotundus root (which is synonymous with *Cyperus rotundus* rhizome), Chinese angelica root (which is synonymous with *Angerica polymorpha* root), ligusticum root (which is synonymous with *Ligusticum wallichii* root), corydalis tuber (which is synonymous with *Corydalis turtshchaninovii* rhizome) and licorice (which is synonymous with *Glycyrrhiza uralensis*), which reads on claim 10, since the plant itself inherently contains extracts.

Gong does not teach a composition comprising Chi Shao (*Paeonia obovata*) root, Dang Gui (*Angelica polymorpha*) root, Chuan Xiong (*Ligusticum wallichii*) root, Xiang Fu

Art Unit: 1655

(*Cyperus rotundus*) rhizome, Yah Hu Suo (*Corydalis turtshanovii*) rhizome and Tao Ren (*Prunus persica*) seed. However, Cai teaches an oral Chinese medicine for curing gynecopathy, such as the diseases of irregular menstruation, menstrual molimen and female sterility, which are all diseases occurring in women, comprising red peony root (which is synonymous with *Paeonia obovata* root), Chinese angelica root (which is synonymous with *Angerica polymorpha* root), nutgrass flatsedge rhizome (which is synonymous with *Cyperus rotundus* rhizome), corydalis tuber (which is synonymous with *Corydalis turtshanovii* rhizome) and licorice (which is synonymous with *Glycyrrhiza uralensis*), which reads on claim 10, since the plant itself inherently contains extracts.

Li teaches a medicine for obstruction of woman's oviduct containing Chinese angelica (which is synonymous with *Angerica polymorpha*), red peony (which is synonymous with *Paeonia obovata*) and peach seed (which is synonymous with *Prunus persica* seed).

Zhang teaches a Chinese medicine in the form of an oral liquor for treating female infertility comprising peach kernel (which is synonymous with *Prunus persica* seed), Chinese angelica root (which is synonymous with *Angerica polymorpha* root), ligusticum root (which is synonymous with *Ligusticum wallichii* root), cyperus root (which is synonymous with *Cyperus rotundus* rhizome), and fennel fruit, wherein an extract is obtained by pulverizing, decocting and filtering the ingredients, which reads on pharmaceutically acceptable extracts (claim 12), which reads on claim 10, since the plant itself inherently contains extracts.

Gong does not teach a composition in the form of a liquid; however, Jenkins teaches that oral liquids have the advantage over solids of being easier to swallow and over tablets of having more rapid bioavailability (See page 59, "Oral liquids").

Beckman teaches that the way in which a drug is administered influences the effects achieved and that there are many factors in determining the appropriate form of administration (See page 38, "Route of Administration").

Therefore, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the composition taught by Gong to provide the instantly claimed invention because at the time the invention was made, the ingredients claimed by Applicant were known to be useful for the same purpose

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach Chi Shao (*Paeonia obovata*) root, Dang Gui (*Angelica polymorpha*) root, Chuan Xiong (*Ligusticum wallichii*) root, Xiang Fu (*Cyperus rotundus*) rhizome, Yah Hu Suo (*Corydalis turtschaninovii*) rhizome and Tao Ren (*Prunus persica*) seed are effective ingredients in compositions for treating gynecopathy, such as female infertility, it would have been

obvious to combine these plants with the expectation that such a combination would be effective in treating gynecopathy. Thus, combining them flows logically from their having been individually taught in prior art.

It is noted that the references do not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to combine the ingredients taught by Gong, Cia, Li and Zhang to provide the instantly claimed invention because the ingredients were all known in the art to have the same function

Art Unit: 1655

effect and it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the form in which the composition is administered, as clearly taught by Jenkins and Beckman.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant argues that the references fail to teach the claimed invention and that claim 1 is novel and a non-obvious combination of herbs that includes a core base of herbs plus additional herbs that have been found to be beneficial and improved the side effects of adenomyosis, endometriosis and dysmenorrhea. Applicant further argues that the references do not teach the specific ingredients claimed by Applicant.

However, this is not found persuasive for the reasons provided in the previous Office Action and for the reasons provided above. First of all, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21

USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner has shown that all of Applicant's claimed ingredients were known in the art to be useful for the same purpose, as clearly set forth above. Furthermore, with regards to Applicant's argument regarding core herbs, please note that the claims do not recite "core herbs" and additional herbs. However, it does not appear that there is support for this concept in the specification, so it is not recommended that Applicant change the language of the claims to recite this, if there is not proper support. Finally, it should be noted that Applicant provides specific combinations of ingredients in specific amounts that have the effect of treating the three conditions in Table 2 and that this specific combination and amounts are not recited in the claims. However, as mentioned before, the ingredients as claimed are known in the art to be useful for the same purpose and are known to be combinable, as clearly demonstrated in the previous Office Action and as demonstrated above. Therefore, the rejection stands for reasons of record.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit: 1655

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May 28, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655